OCT 0 6 2008

SPECIAL 510(K) SUMMARY

LYMPHA PRESS OPTIMAL MODEL 1201AP

COMPRESSIBLE LIMB SLEEVE DEVICE

510(k) Number K082149

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Date Prepared: July 2008

Trade Name: Lympha Press Optimal Model 1201AP Compression Therapy Device

Device Common or Usual Names: Compressible Limb Sleeve

Classification Name: CFR Classification section 870.5800 (Product code JOW)

Classification: Class II medical Device

Predicate Device: The Lympha Press Optimal Model 1201AP Compression Therapy Device is substantially equivalent to the following predicate device:

- Lympha Press Plus Model 1033AL (K013331) manufactured also by Mego Afek AC, Ltd (Israel). Lympha Press Plus is a compressible limb sleeve, similar to the Lympha Press Optimal Compression Therapy Device.

Device Description: Mego Afek's Lympha Press Optimal Model 1201AP Compression Therapy Device is a modification of the original Lympha Press Plus device. It utilizes a software controlled air compression pump, which sequentially inflates and deflates cells within a compression garment (sleeve) that is put around a limb. This helps to push excessive interstitial fluid in the treated limb, back into the venous and lymphatic systems; improve limb circulation; and thus treat the symptoms of a variety of lymphatic disorders, venous disorders and dysfunction of the "muscle pump". The device consists of a main console and compression garments. The main console contains an air compressor that is regulated by an electro-mechanical mechanism, including pressure sensors and a rotating disc controlling air outflow. The regulated compressed air is transferred via an air distributor through a series of hoses to the sleeve garments. In the Model 1201 device, each garment contains up to 12 overlapping pressure cells. The sleeve fits on the affected limb and can be easily adjusted to any limb size within the sleeve tolerance.

Intended Use / Indication for Use: The Lympha Press Optimal is intended for the following Indications for Use:

Primary lymphedema (for example, congenital lymphedema/ milroy's disease)

Secondary lymphedema (for example, post-mastectomy, chronic edema, post-traumatic edema)

Venous disorders (for example, venous insufficiency, varicose veins, venous stasis ulcers)

Dysfunction of the muscle pump (for example, promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries)

The device is intended to be used by the patient at home, as well as by physicians at clinics or hospitals.

Performance Standards:

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for a compressible limb sleeve device.

Test Data: The Lympha Press Optimal Model 1201AP Compression Therapy device has been subjected to extensive safety, performance testing, and validation before release, as required by the risk analysis performed for device modifications. Final testing of the Model 1201AP Compression Therapy device included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards.

Substantial Equivalence: The Lympha Press Optimal Model 1201AP Compression Therapy device is similar to currently distributed Compression Therapy devices intended for treatment of venous and lymphatic disorders and dysfunction of the "muscle pump". The device uses sequential inflation and deflation of cells within compression sleeves put around a limb. Inflation/ Deflation pressures and sequences are similar to those of predicate devices. Operating modes are similar to those of predicate devices. All of the above features are similar to these features in the predicate devices.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices is that the Lympha Press Optimal Model 1201AP compression therapy device is substantially equivalent in safety and efficacy to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 6 2008

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Re: K082149
Lympha Press Optimal™, Model # 1201AP
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: July 27, 2008
Received: July 30, 2008

Dear Dr. Hornick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082149

Device Name: Lympha Press Optimal (Model 1201AP) Compression Therapy device

Indications for Use:

- **Primary lymphedema (for example, congenital/ milroy's disease)**
- **Secondary lymphedema (for example, post-mastectomy, chronic edema, post-traumatic edema)**
- **Venous disorders (for example, venous insufficiency, varicose veins, venous stasis ulcers)**
- **Dysfunction of the muscle pump (for example, promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries)**

The device is intended to be used by the patient at home, as well as by physicians at clinics or hospitals.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082149